IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Fisher, Paul B.	
Serial No.	:	09/933,115	Examiner: Angell, Jon E.
Filed	:	August 20, 2001	Group Art Unit: 1635
For	:	COMBINATORIAL METHODS FOR INDUCING CANCER CELL DEATH	

RESPONSE

I hereby certify that this paper is being deposited on August 21, 2003 with the United States Postal Service as first class mail in an envelop addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Lisa B. Kole
Attorney Name

Signature

35,225
PTO Registration No.

December 4, 2003
Date of Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action dated October 6, 2003, please consider the following remarks. Applicant submits herewith (1) a Petition for Extension of Time for a period of one month, up to and including Monday, December 8, 2003, together with the appropriate fee and (2) a Second Supplemental Information Disclosure Statement, together with cited references.

In the Official Action, the Examiner has required that Applicant elect one among five listed inventions, as follows:

Group I: claims 2-4, 12-14, 22-24, and 32-34, drawn to a method for inhibiting proliferation and inducing cell death in a population of cancer cells by increasing the amount of differentiation associated protein MDA-7 using a nucleic acid encoding MDA-7 and decreasing RAS activity within the population;

Group II: claims 43 and 44, drawn to a method of identifying candidate cancer cells for treatment;

Group III: claim 45, drawn to a viral vector comprising a nucleic acid encoding MDA-7 protein and a nucleic acid encoding an antisense ras nucleic acid;

Group IV: claim 47, drawn to a method for inhibiting the proliferation of a cancer cell by introducing isolated MDA-7 protein; and

Group V: claims 48-50, drawn to a method for inhibiting the proliferation of a cancer cell by introducing a nucleic acid encoding MDA-7 protein, which is then secreted.

In addition, if Applicant elects Group I, he is required to select one each from two subgroups of subject matter, as follows:

Subgroup 1:

A) an antisense molecule;

B) a ribozyme;

C) a precursor of a triple helix; and

D) a farnesyl transferase inhibitor.

Subgroup 2:

i) an agent which inhibits the EGF receptor;

ii) an agent which inhibits MAP kinase;

iii) an agent which inhibits MAPK kinase; and

iv) an agent which inhibits P13 kinase.

The Examiner states:

> Claims 1, 11, 21, 31 and 41 link(s) the inventions of Groups I:A-D and i-iv; claims 5, 15, 25 and 35 link(s) the inventions of Groups I:A-D; claims 6-9, 16-19, 26-29 and 36-39 link(s) inventions I:A and i-iv. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claims(s). Upon allowance of the linking claims(s), the restriction requirement as to the linked invention shall be withdrawn and any claims(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant respectfully traverses the restriction requirement for the following reasons.

The crux of the present invention is the discovery that the combination of increased MDA-7 with decreased RAS activity is particularly effective in inhibiting the proliferation and inducing the death of cancer cells, especially cancer cells having a mutant ras gene. For that reason, Applicant believes that Groups I and III should be combined, because Group I relates to the method of combined therapy and Group III relates to a vector that may be used according to such method, whereby the vector encodes MDA-7 protein as well as an antisense nucleic acid that decreases RAS activity. Applicant believes that the search required would be the same for Groups I and III, so there would be no extra burden on the Examiner to consider these groups together.

In addition, Applicant respectfully disagrees with the requirement that one member of each of *two* subgroups of Group I be selected, and requests the Examiner to consider that it would be more appropriate to have a single subgroup. It appears that the intention of the Examiner is to distinguish categories of subject matter by the way in which RAS is inhibited. Indeed, subgroup 1, categories A-D, and subgroup 2, categories i-iv, are all ways in which RAS can be inhibited, and should be in a single group. The requirement that Applicant select one of both subgroups prohibits Applicant from pursuing claims directed to the working example, where an antisense molecule with sequence complementarity to ras nucleic acid acts directly on RAS and only indirectly inhibits the EGF receptor, MAP kinase, MAPK kinase, and P13 kinase. It would seem that if Applicant selects antisense molecules from the first subgroup, then selection of one of subgroups i-iv would mean that an antisense approach would be used to inhibit either the EGF receptor, MAP kinase, MAPK kinase, or P13 kinase rather than ras itself, which is not the preferred embodiment of the invention.

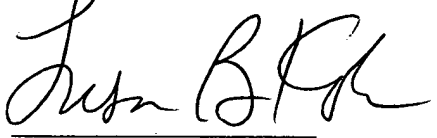
Therefore, Applicant requests that the restriction requirement be revised to combine Groups I and III and subgroups A-D and i-iv. If Applicant's request is granted, Applicant would elect to pursue the invention of Groups I and III and, as a subgroup, antisense molecules. Applicant notes that the selection of antisense molecules as a species supports the combination of Groups I and III, as the vector of Group III encodes an antisense molecule. Claims that read on such an election are claims 1-9, 11-19, 21-29, 31-39, 41, 42 and 45 It is Applicant's understanding that should the elected claims be found to be patentable with respect to antisense molecules, the examination would be extended to other means of inhibiting RAS. Further, such election would be made

without prejudice to the prosecution of subject matter of non-elected claims in other applications.

If the Examiner does not agree to revise the restriction requirement, then Applicant elects to pursue the claims of Group I in this application, without prejudice to the prosecution of claims directed to non-elected subject matter in other patent applications. As regards subgroup 1, Applicant elects (A), antisense molecules. With regard to subgroup 2, Applicant elects subgroup (i), agents that inhibit the EGF receptor. Claims that read on these elections are claims 1-42.

An early allowance is earnestly requested.

Respectfully submitted,



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